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| <b>(54) Title:</b> TREATMENT FOR CUTANEOUS PAIN, ITCHING AND INFLAMMATION WITH TOPICAL STANNOUS FLUORIDE<br><br><b>(57) Abstract</b><br><br>The present invention provides a treatment for the cutaneous pain, itching and inflammation associated with allergies, burns, trauma, insect bites and bacterial, viral and fungal infections. According to the invention, a non-toxic amount of stannous fluoride is incorporated into a suitable pharmaceutical carrier and administered topically.                                  |           |  |

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TREATMENT FOR CUTANEOUS PAIN, ITCHING AND INFLAMMATION  
WITH TOPICAL STANNOUS FLUORIDE

5

BACKGROUND OF THE INVENTION

10 The present invention relates to a treatment for the cutaneous pain, itching and inflammation often associated with allergies, burns, trauma, insect bites and bacterial, viral and fungal infections. More particularly, the invention relates to the topical application of stannous fluoride for the treatment of such symptoms.

15 A large number of pharmaceutical preparations, as well as other forms of treatment, have been developed for administration to patients suffering from the pain, itching or inflammation which accompanies allergies, burns, infections and the like. Antihistamines, analgesics, corticosteroids and astringent dressings are typical of such treatments. However, it is often the case that such treatments are either ineffective or marginally effective, have associated undesirable side effects or are prohibitively expensive, especially when long term administration is required.

20 It is, therefore, an object of the present invention to provide a treatment for cutaneous pain, itching and inflammation which is effective, safe and inexpensive.

SUMMARY OF THE INVENTION

25 The present invention meets this object by providing a treatment which includes the topical application of stannous fluoride. A non-toxic amount of stannous fluoride is incorporated into a pharmaceutical carrier, such as a gel, ointment, cream, lotion or the like, and applied at the site of the inflammation, itching or lesion. Preferably, the stannous fluoride is provided in a concentration  
30 ranging from about 0.1 wt. % to about 8 wt. %. Most preferably, the stannous fluoride is applied as a 0.4% SnF<sub>2</sub> glycerin-based gel. The frequency of application may range anywhere from one to six times a day or on an as needed basis. The course of therapy typically ranges from one to ten days but may be continued as long as required for complete relief.

35

### DETAILED DESCRIPTION OF THE INVENTION

A non-aqueous stannous fluoride gel is prepared by solubilizing  $\text{SnF}_2$  in glycerin at approximately  $150^\circ\text{F}$  for four hours. The resulting gel is a stable  
5 solution having an indefinite shelf life that is ideal for topical application to the skin and mucosal tissues. As the following examples demonstrate, stannous fluoride promotes relief from pain, itching and inflammation; however, the mechanism by which the compound effects these results is not clearly understood. It is  
10 hypothesized that both tin ( $\text{Sn}^{++}$ ) and fluoride ( $\text{F}^-$ ) ions interact together and affect nerve action potentials, histamine release, cellular enzyme systems and vascular systems, all of which can influence the pain, itching and inflammation caused by infection, allergies and trauma.

#### EXAMPLE 1

Two patients exhibiting an allergic reaction to poison ivy were instructed to  
15 apply 0.4%  $\text{SnF}_2$  gel 4 to 6 times a day or on an as needed basis. Relief from pain and itching was obtained almost immediately.

#### EXAMPLE 2

Five patients with burns were instructed to apply 0.4%  $\text{SnF}_2$  gel 4 to 6  
20 times a day or on an as needed basis. Relief from the pain associated with the burns was obtained almost immediately.

#### EXAMPLE 3

Ten patients having insect bites (7 mosquitoes, 2 bees) received immediate relief from the associated pain, inflammation and itching when 0.4%  $\text{SnF}_2$  gel was applied.

25

#### EXAMPLE 4

Three patients received pain relief from cuts on the skin when 0.4%  $\text{SnF}_2$  gel was applied to the lesions.

#### EXAMPLE 5

Fifteen patients infected with herpes zoster virus and 30 patients infected  
30 with herpes simplex virus were instructed to apply 0.4%  $\text{SnF}_2$  gel 4 to 6 times a day. The pain and itching associated with the infections was either eliminated completely or significantly reduced.

#### EXAMPLE 6

Eight patients having acne infections of bacterial origin on the skin obtained  
35 relief from the pain associated with the infections when 0.4%  $\text{SnF}_2$  gel was applied.

EXAMPLE 7

Two patients infected with ringworm and eight patients infected with athletes foot were instructed to apply 0.4% SnF<sub>2</sub> gel 4 to 6 times a day or on an as needed basis. Relief from the itching and pain associated with the infections was  
5 obtained almost immediately.

While preferred embodiments have been shown and described, various modifications and substitutions may be made without departing from the spirit and scope of the invention. Accordingly, it is to be understood that the present invention has been described by way of example and not by limitation.

What is claimed is:

1. A method of treating cutaneous pain, itching and inflammation comprising: topically applying a non-toxic amount of stannous fluoride  
5 incorporated into a pharmaceutical carrier.
2. The method of claim 1 further characterized in that the stannous fluoride is provided in a concentration ranging from about 0.1 weight percent to about 8 weight percent.  
10
3. The method of claim 1 wherein the pharmaceutical carrier is a gel, ointment, cream or lotion.
4. The method of claim 1 further characterized in that the stannous fluoride  
15 is applied as a 0.4 weight percent glycerin-based gel.

## INTERNATIONAL SEARCH REPORT

 International application No.  
 PCT/US93/05812

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) : A61K 31/765

US CL : 424/486

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/486, 650

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| Y         | US, A, 4,563,489 (URIST) 07 JANUARY 1986 See entire document.                      | 1-4                   |
| Y         | US, A, 4,639,366 (HELLER) 27 JANUARY 1987 See entire document.                     | 1-4                   |
| Y         | US, A, 5,013,649 (WANG) 07 MAY 1991 See entire document.                           | 1-4                   |
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